Heritage Information Systems, Inc.

Drug Monograph

Drug/Drug Class: Oxandrin®

Prepared for: Missouri Medicaid
Prepared by: Heritage Information Systems, Inc.

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose: The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, or require prior authorization for use.

Dosage Forms & Manufacturer: Oxandrin® is an anabolic steroid manufactured for BTG Pharmaceuticals. It is available as 2.5 and 10mg tablets.

Summary of Findings: Oxandrin® is indicated as adjunctive therapy to promote weight gain after involuntary weight loss, to counterbalance the protein catabolism associated with chronic corticosteroid administration, and for the relief of osteoporosis-related bone pain. Because of the costs associated with therapy and the need to reevaluate its efficacy and side effects on an ongoing basis, it is not recommended that Oxandrin® be available as open access.

Status Recommendation:
☐ Prior Authorization (PA) Required ☐ Open Access
☒ Clinical Edit

Type of PA Criteria:
☐ Increased Risk of ADE ☒ Non-Preferred Agent
☐ Appropriate Indications ☐ PA Not Required

Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug or not (open access). While prescription expenditures are increasing at double-digit rates, payors are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

Introduction

Anabolic-androgenic steroids, more commonly referred to as "anabolic steroids," are synthetic derivatives of testosterone. [1,2] There are currently three anabolic steroids available in the U.S.: oxandrolone (Oxandrin®), oxymetholone (Anadrol®), and stanozolol (Winstrol®). Although these agents have similar properties and side effect profiles, they are each have their own unique indications. Oxandrin® is mainly utilized to promote weight gain.

Dosage Form(s)

Oxandrin® is available as 2.5and 10mg tablets.[1]

Manufacturer

BTG Pharmaceuticals, Iselin, NJ

Indication(s)

Oxandrin® is indicated as adjunctive therapy to promote weight gain after involuntary weight loss, to counterbalance the protein catabolism associated with chronic corticosteroid administration, and for the relief of osteoporosis-related bone pain. Disorders involving involuntary weight loss include HIV, burns, nonhealing wounds (e.g., lower extremity ulcerations), spinal cord injury and trauma.[1]

Clinical Efficacy (mechanism of action/pharmacology, comparative efficacy)

Oxandrin® is a synthetic derivative of testosterone, which has been shown to have anabolic and androgenic effects. The anabolic activity involves an increase in protein synthesis, which results in greater muscle mass and strength. The androgenic effects of testosterone lead to the growth of the male reproductive tract, as well as the development of secondary sexual characteristics. Because of an interest to isolate the anabolic activity of testosterone, derivatives with less androgenic effects (such as Oxandrin®) were developed.[1,2]

In comparison to testosterone, Oxandrin® has ten times the anabolic activity, and only one-tenth the androgenic activity. Studies have shown it to be effective in the treatment of various catabolic conditions, including hepatitis and AIDS. According to the manufacturer, two to four weeks of therapy is usually sufficient and may be repeated intermittently.[3] Weight changes should be monitored occasionally to determine the efficacy of therapy.[1]

Adverse Effects

Some of the side effects associated with anabolic steroid use include:

- Hepatotoxicity (including elevated liver enzymes, cholestatic jaundice, peliosis hepatic),
- masculinization in women and children (e.g., deepening of voice, hirsutism),
- edema,
- premature closure of epiphysis in children,
- depression,
- hypomania,
- changes in lipid levels, and
- glucose intolerance.[2]

Drug Interactions[1]

Oral anticoagulants – Patients receiving Oxandrin and oral anticoagulants (e.g., warfarin) may experience an increase in their prothrombin time.
Oral hypoglycemic agents – The concomitant use of these agents can lead to hypoglycemia.

Dosage and Administration

Adults:
2.5-20mg daily (in 2-4 divided doses)

Children:
≤0.1mg/kg or ≤0.045mg/pound of body weight

Cost Comparison (at commonly used dosages[4])

Selected Product Comparison:

Product	AWP/HCFA* per 30 days
Oxandrin	$1038-1048
Marinol	$265
Megestrol acetate (generic)	$405
Thalomid	$2274

*Average Wholesale Price: Facts and Comparisons (Medi-Span), St Louis, MO; November 2002. Costs rounded to the nearest whole dollar. HCFA maximum allowable charge (MAC) is used for generic drugs when available.

Conclusion

Oxandrin® is indicated as adjunctive therapy to promote weight gain after involuntary weight loss, to counterbalance the protein catabolism associated with chronic corticosteroid administration, and for the relief of osteoporosis-related bone pain. Because of the costs associated with therapy and the need to reevaluate its efficacy and side effects on an ongoing basis, it is not recommended that Oxandrin be available as open access.

Recommendation(s)

It is recommended to include Oxandrin® as a clinical edit.

References

1) BTG Pharmaceuticals. http://www.oxandrin.com/hiv/about/ox_prod_info.html. Accessed 11/26/02.
2) Shahidi NT. A review of the chemistry, biological action, and clinical applications of anabolic-androgenic steroids. Clin Ther 2001;23(9):1355-90.
3) Basaria S, Wahlstrom JT, Dobs AS. Clinical review 138: Anabolic-androgenic steroid therapy in the treatment of chronic diseases. J Clin Endocrinol Metab 2001;86(11):5108-17.
4) Balog DL, Epstein ME, Amodio-Groton MI. HIV wasting syndrome: treatment update. Ann Pharmacother 1998;32:446-58.

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